K041881

MAR 2 5 2005

510(k) Summary

1. SUBMITTED BY:

Bruce A. MacFarlane, Ph.D.
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis, MN 55439
USA

Summary prepared: 28 February 2005

2. NAME OF DEVICES:

Trade Names:
Advance Micro-draw™ Glucose Monitoring System
Advance Micro-draw™ Test Strips
Advance Micro-draw™ High Control Solution
Advance Micro-draw™ Normal Control Solution

Common Names/Descriptions: Blood glucose monitoring system

Classification Names:
- Glucose test system, product codes CGA & NBW, 21 CFR 862.1345
- Single (specified) analyte controls (assayed/unassayed), product code JJX, 21 CFR 862.1660

Regulatory Status: Class II

PREDICATE DEVICE: LifeScan OneTouch® Ultra® Blood Glucose Monitoring System[1]

3. DEVICE DESCRIPTION:

The Advance Micro-draw™ Blood Glucose Monitoring System consists of a meter, test strips, and control solution. It is intended for over-the-counter, home use by diabetics to monitor their blood glucose levels, or for use in a clinical setting by health care professionals. The system tests fresh capillary whole blood. The meter is a portable, battery-operated instrument designed for use with Advance Micro-draw™ Blood Glucose Test Strips.

[1] OneTouch and Ultra are registered trademarks of LifeScan, Inc.

4. INTENDED USE:

The Advance Micro-draw™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

5. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Advance Micro-draw™ Blood Glucose Monitoring System is technically unchanged by this expansion of indications (claiming palm in addition to fingertip testing). The Advance Micro-draw™ trade name was "Hypoguard Advance™" at the time of initial premarket notification.

6. NON-CLINICAL TESTING

Not Applicable

7. CLINICAL TESTING

Accuracy/method correlation testing was done comparing fingertip results obtained by clinicians with alternate site results obtained by participants with diabetes.

Testing included both men and women, both Type 1 and Type 2 diabetes, ages from twenty to seventy-eight. Tested blood glucose values encompassed the 51-435 mg/dL glucose range. Linear regression statistics showed good correlation between fingertip and alternate site results.

8. CONCLUSIONS FROM TESTING

Testing demonstrated that the performance of Advance Micro-draw™ at the claimed alternate site was substantially equivalent to that at fingertip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 5 2005

Bruce A. MacFarlane, Ph.D.
Vice President, Regulatory Affairs and Quality Systems
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis, MN 55439

Re: k041881
Trade/Device Name: Advance Micro-draw™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: February 28, 2005
Received: March 1, 2005

Dear Dr. MacFarlane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041881

Device Name: Advance Micro-draw™ Blood Glucose Monitoring System

Indications For Use:

Advance Micro-draw™ Blood Glucose Monitoring System:

The Advance Micro-draw™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Advance Micro-draw™ Blood Glucose Test Strips:

Advance Micro-draw™ Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Advance Micro-draw™ Test Strips must be used with the Advance Micro-draw™ Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Advance Micro-draw™ Control Solution:

For use with Advance Micro-draw™ Blood Glucose Meter and Advance Micro-draw™ Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

510(k) K041881